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Intellectual Property Protection For Agricultural Biotechnology: A Survey On The Malaysian Research Institutes' Experiences And Legal Policy

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ABSTRACT

This article focuses on the current legal protection for agricultural biotechnological inventions in Malaysia. As far as Malaysian IP system is concerned, there are two main regimes which are currently in force: patent law and plant variety protection law. Patent law in Malaysia refers to the Patents Act 1983, supplemented by the Patents Regulations 1986, while plant variety protection law in Malaysia is governed by the Protection of New Plant Varieties Act 2004 (PNPVA), supplemented by the Protection of New Plant Varieties Regulations 2008.The discussion is mainly based on the data which has been collected via semi-structured interviews with a number of selected public sector research institutions. The selected research institutions represent a large component of the views of plant breeders in Malaysia. The interviews sought to collect the data in respect of the extent of use of the IPRS, the level of awareness, appropriateness and effectiveness of the existing legal protection. The response was to some extent an indicative of the views of those involved in the industry and R&D of agricultural biotechnology. Besides, the interviews had been of great assistance to identify those areas where further legislative activity might be needed. The patent regime seems to be preferred by the majority of the RIs for the reason that it offers strong and reliable protection over inventions, while the effectiveness of protection offered under the Protection of New Plant Varieties Act 2004 is yet to manifest despite the fact that it is specifically tailored for breeders of new plant varieties in Malaysia. In short, the overall finding is that the Malaysian biotechnology industry is on track to accelerate commercialization in biotechnology with the full support of the National Biotechnology Policy and BiotechCorp.

Key words: IPR, patent, plant variety right, research institutes, agricultural biotechnology

Introduction

The Malaysian biotechnology industry is dominated by small-to-medium sized companies with a handful of larger players, such as those running plantations, which have developed strong research and development (R&D) arms within their corporations. As far as research activities are concerned, biotechnology research in Malaysia is mainly undertaken by public sector institutions such as MARDI (The Malaysian Agricultural Research and Development Institute), FRIM (The Forest Research Institute Malaysia), MPOB (The Malaysian Palm Oil Board), MRB (The Malaysian Rubber Board) and MCB (The Malaysian Cocoa Board). The private sector's involvement in agricultural biotechnology is primarily focused *inter alia* on plant tissue and cell culture. This ranges from the production of ornamental plants such as orchids and pitcher plants, herbal plants which have medicinal uses, to mass-propagated top-of-the line plants.

Materials and Methods

The focus of this article is on the current position of intellectual property protection for agricultural biotechnology in Malaysia based on the data which has been collected via semi-structured interviews with a number of public sector research institutions. The selected research institutions (RIs) as mentioned above represent a large component of the views of plant breeders in Malaysia. The selection of the above respondents was justified on the basis that the main industrial crops in Malaysia are oil palm, rubber and cocoa, of which the research work is undertaken by MPOB, MRB and MCB respectively, whereas the research activities for other types of plants such as rice, banana, coconut, papaya and so forth are entrusted to MARDI. The questions for the semi-structured interview were drafted with the main aim to assess *inter alia* the extent of use, awareness, appropriateness and effectiveness of the existing legal protection vis-à-vis intellectual property rights (IPRs) available to those involved in agricultural biotechnology.

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Results:

The response to the interview, which includes the data collected throughout the research period, was to some extent an indicative of the views of those involved in the industry and R&D of agricultural biotechnology. In addition, the interviews had managed to identify those areas where further legislative activity might be needed.

Discussion on biotechnology research activities: the current status and focus:

Genetic modification research in Malaysia mainly involves crop improvement work, especially in relation to developing pest and disease tolerant crop varieties, high-yielding and value added crop varieties. To date, there is no record of a commercial variety being released for commercial planting that has been genetically modified using recombinant DNA technology. In Malaysia, there are several commercial crops being studied or being modified genetically, for example papaya, rice, and chili by MARDI, oil-palm by MPOB, cocoa by MCB, rubber tree by MRB and teak by FRIM.

It is of paramount importance to ascertain and identify the types of biotechnology research undertaken by the RIs and relevant bodies, as it would be indicative and reflective of the research trends in Malaysia. The relevant question to be answered is whether R&D in those RIs is focusing on 'gene' from its very basic stage, or whether the RIs research teams are merely replicating and applying the current available biotechnology in plant biotech worldwide. It was discovered based on the interviews and various online sources that generally, most research activities in those RIs focus on genetic engineering for crop improvement, disease and herbicide resistance and value added products. In this regard, some of the technologies used are inevitably based on existing plant biotechnology which has been proven a success in the industrialized countries such in the U.S. and Europe.

One relevant example would be the application of *Bacillus thuringiensis* (*Bt*) transgenic technology to various plants in Malaysia, such as rice, papaya, sweet potato and the like. The research is on-going, hence it remains to be proven whether *Bt*-transgenic technology would work and be effective for other types of crops than corn and cotton. On the global stage, the majority of commercially released transgenic plants are currently limited to plants that have introduced resistance to insect pests and herbicides. Insect resistance is achieved through incorporation of a gene from *Bt* that encodes a protein that is toxic to some insects. For example, if the cotton bollworm, a common cotton pest, feeds on *Bt*-cotton it will ingest the toxin and die. Herbicides usually work by binding to certain plant enzymes and inhibiting their action. The enzymes that the herbicide inhibits are known as the herbicides target site. Herbicide resistance can be engineered into crops by expressing a version of target site protein that is not inhibited by the herbicide. This is the method used to produce *glyphosate* resistant crop plants. In this regard, insect-protected plants containing a natural insecticide protein from *Bt* (for example *Bt*-cotton and *Bt*-corn) have successfully provided millions of farmers worldwide with increased yields, reduced insecticide costs and fewer health risks. Hence, it is not surprising for a developing country such as Malaysia to apply similar technology in order to enhance specific plants for the benefit of local farmers and consumers. At this juncture, it is worth noting that public RIs in Malaysia are actively researching the application of *Bt*-transgenic technology for target plants and crops. For instance, disease and herbicide resistant varieties in rice and cassava as undertaken by MARDI's research team.

The research emphasis of respective RIs is summarized in the following table.

Table 1: The area of research emphasis of major RIs in Malaysia.

RIs	Research Emphasis
Malaysian Agricultural Research and Development Institute (MARDI)	(i)Delayed ripening in papaya (ii)Disease resistance in rice, chilli, papaya and sweet potato (iii)Floral colour in orchids (iv)Improved quality and nutrition in rice, cassava and sweet corn (v)Yield improvement and herbicide resistance in rice
Malaysian Palm Oil Board (MPOB)	(i)Yield improvement (ii)Improved oil quality (iii)Production of biodiesel (iv)Research on oil palm genomes
Malaysia Rubber Board (MRB)	(i)Disease resistance (ii)Production of high-value protein
Malaysian Cocoa Board (MCB)	(i)Disease resistance (ii)Yield improvement (iii)Production of specialty cocoa trees
Forest Research Institute of Malaysia(FRIM)	(i)Delayed flowering and disease resistance in teak

The knowledge and understanding of the current nature, research focus and R&D activities undertaken and carried out by those RIs in Malaysia is vital to ascertain the suitable, best IP protection for the R&D yields and

output. This is because plant breeders, researchers and investors in Malaysia presently have the option under patent laws or plant variety rights; either or both types of protection that best suit their needs to protect their inventions.

The significance of agricultural biotechnology R&D activities:

All research institutes which play significant roles in agricultural biotechnology R&D in Malaysia have their own specific unit or division to run their biotechnology research activities. This is parallel to the Government's aspiration and mission to boost the local biotechnology sector. In fact, effective R&D is one of the Government's primary initiatives towards harvesting the potential of biotechnology as a growing source of the country's wealth creation.

The RIs like MARDI, MRB and MCB are backed by Government funding and budget allocation to maintain their operation and R&D, whereas MPOB derives its funding mainly from acess imposed on the industry for every tonne of palm oil and palm kernel oil produced. Nevertheless, in addition, MPOB receives budget allocations from the government to fund development projects and for approved research projects under the Intensification of Research in Priority Areas (IRPA) programme. MRB similarly imposes cess on natural rubber production as part of its funding sources, other than the budget allocations from the Government.

It is essential to ascertain the sources of funding of the RIs as it would affect and shape their R&D activities on a wider perspective. The relevant discussion on this matter follows in the latter part of this chapter.

The following table summarizes the finding of the semi-structured interviews with regard to the data on biotech-related R&D of the RIs:

Table 2: The summary of finding collected during the semi-structured interview.

Research Institutes / Organization (RIs)	Years of involvement in biotechnology	Percentage of employees involved in biotech R&D	Percentage of financial resources for biotech R&D	Plant species
MARDI	20	> 50	NA	All crops except palm oil, rubber, cocoa
MPOB	40	20	NA	palm oil
MRB	20	15	>10	rubber
MCB	9	15	>10	cocoa
FRIM	10	10	10	Forestry (acacia, teak, rattan, bamboo etc) herbs

All RIs interviewed have their own specific unit or division dealing with research in agricultural biotechnology. Being RIs, all of them have been involved in biotechnology research since their establishment; this is very true as the term biotechnology in general encompasses both 'conventional' and 'modern' biotechnological revolution. After all, their long research involvement in agricultural biotechnology is not surprising as it is one of the most promising developments in modern science, in addition to the fact that Malaysia is well endowed with natural resources in agriculture.

Research in agricultural biotechnology as being undertaken by these RIs revolves around the genetic improvement of industrial crops and plant varieties, agricultural genomics, as well as tissue culture technology in transgenic crops and forest trees. There are in fact a number of ongoing researches on genetically modified plants but all are still at the experimental stage, as confirmed by MARDI. Other key research areas for the agriculture sector include livestock farming, animal health and nutrition, bio-pesticides and bio-fertilizers, extraction of metabolites and nutritionally enhanced agriculture products.

The significance of biotechnology research is represented in the percentage of the employees and researchers involved in the research, as well as the funding or budget allocation for such activities as shown in Table 5.1. The percentage of employees committed to agricultural biotechnological research in the RIs ranges from 10 to 50 percent, evidencing the growing importance and prominence of biotechnological industry in Malaysia. In relation to this, the Government of Malaysia in its Ninth Malaysia Plan allocates a total of RM 2 billion funding for biotechnology sector which includes physical and soft infrastructure.

Patenting Activities:

Biotechnology is a product of human efforts and innovation and can only develop in a condition with solid scientific and technological background. The response from the RIs during the interview sessions reveals that

patenting activities have been an important part of their integrated role in R&D. The following table essentially summarizes their patenting work.

Table 3: Statistic of patenting activities by major RIs in Malaysia.

Research Institutes / Organization (RIs)	The year in which first Malaysian patent application made	Number of current patents (year 2008)	Patents abroad	Number of patents applied annually	Average number of patents granted annually
MARDI	1996	Approved/granted: 3 Filed/Pending: 15	No	5-8	3
MPOB	1980s	Approved/granted: 60 Filed/Pending: 150	Yes	18-20	3
MRB	1934 (first patent applied)	Approved/granted: 119 Filed/pending: 16	Yes	4	2
MCB	2004	Approved/granted: 5 Filed/pending: Not available	Yes	1	1
FRIM	1990	Approved/granted: 19 Filed/pending: 19	Yes	4	2

It is interesting to note that applying for patents seem to be an obligation undertaken by these RIs and agencies. After all, it has become a trend nowadays as patent applications provide a good indicator of technological innovation and capacity performance of an institution or body. It is clear from Table 3 that patenting activities in these research institutions have taken place as early as 1934 when MRB applied for its first patent. However, as far R&D in local biotechnology is concerned, patenting works has started to gain momentum in 1980s and 1990s.

MRB for instance started its work on genetic transformation of rubber cells in the year 1990. In fact, MRB has been very active in their biotechnology research, focusing *inter alia*, on the transgenic rubber tree research with the aim of improving rubber tree productivity. The transgenic rubber tree stands to gain a wide variety of desirable agronomic traits. High latex and timber yield are some of the areas that the rubber industry stands to gain and to serve the latex based sectors and the wood based industries.

Based on the figures in the Table 3, it is very clear that MPOB has been the most active institution in patenting activities. It has 60 approved patents, while 150 applications are still pending. As a matter of fact, MPOB plays a significant role in applying and promoting oil palm biotechnology in Malaysia. It is one of the most productive agencies in producing technology and new innovations which contribute directly to the palm oil industry. The large number of patents held and applied by MPOB is attributed to the fact that it works directly for the industry players in the local palm oil industry, and their funding operation and revenue is mainly generated from cess collection of palm oil and palm kernel oil produced at the mills and crushers. In addition, MPOB receives budget allocations from the government to fund development projects and for approved research projects. Having said that, MPOB is obviously very active and has shown a strong commitment in its research and development, and this goes parallel with their patenting activities. Interestingly, filing of patent had been a culture for MPOB since the introduction of its IP policy in 1999.

Other than MPOB, MARDI is another important RI in Malaysia, which has been very active in its research activities ever since its establishment in 1971. Nevertheless, most of its research outputs remain in the laboratory as they have not been patented nor commercialized. As far as patent applications are concerned, patenting activities in MARDI has started to gain pace in 1996. MARDI has since been moving gradually from a pure focus on research activities towards a more active approach in terms of patents and commercialization. In fact, MARDI has set up certain targets in terms of achieving its number of patents filed and granted, which is set around 5 to 8 patents annually.

Nevertheless, MARDI is yet to file or hold any patents abroad. This is attributable to the fact that it sees no necessity yet to file international patents to protect their research results, which revolve around new food crops varieties and clones. One of the underlying reasons is the financial factor, as patenting abroad would incur a high cost. As far as patenting is concerned, MARDI has put in a total of 14 patent applications over 10 years (1996-2006). The number is minimal, yet it reflects a positive development and progress in protecting its research via IPRs notably patents.

It is worth noting in comparison to MPOB and MRB who work directly for the industry players and hence very efficacious in patenting their inventions. MARDI is much less aggressive in its patenting activities as there is a lack of takers or investors for its research outputs and inventions. This is further attributed to the fact that most local agriculture-based manufacturers are small and medium-sized companies, with limited financial resources and funding to commercialize MARDI's inventions.

FRIM equally shows an active participation in protecting its inventions via patents, and currently holds 29 patents. As one of the world reputed centres for tropical forestry research, FRIM has more than 100 years of experience in forestry and forest products research. Their patenting activities started in 1990, with a total of 19

patents held currently, though its annual number of patents filed remains minimal. Being one of the twelve mega-diversity countries in the world, FRIM has a very significant role in agro-forestry and biotechnology, researching into plants and forest produces. Some of the plants which are being actively researched into at FRIM include rattan, bamboo, *Eurycoma* herbs and teak.

MCB owns 5 patents (as at year 2008), targeting a minimum of one patent application to be filed annually. Malaysia is Asia's largest cocoa grinder in terms of capacity and volume hence MCB was established in 2004 to focus its research exclusively on the cocoa bean plant. The role played by MCB is important to the development of the cocoa industry in Malaysia to be well integrated and competitive in the global market ultimately. MCB's current biotechnology research in cocoa biotechnology is inevitable to create higher yielding cocoa hybrids in order to assist cocoa farmers to produce more of this precious commodity.

In short, patenting activities that have been taking place in the major RIs in Malaysia to some extent serve as a positive indicator, signifying the increased awareness of IPRs among local breeders to protect their products of research and development. After all, any research in agricultural biotechnology projects is expensive, attracting a large amount of investment and financial resources, as well as being hugely time-consuming. Therefore, IP protection via the patent regime is seen as one of the strongest, justifiable protections for the biotechnological inventions, which include agricultural biotechnology.

As far as Malaysian scenario is concerned, there remains some assertion and perception from general public and NGO's that the products of research and development by research institutions should be freely available since the large portion of the funding comes from the Government. This argument could be met by the fact that even the Government in the long run being the financier and investor would expect a return of investment and making profits or at least to cover the research cost. This is in addition to providing the researchers involved in the research project the extra monetary initiatives and driving force in their research efforts and endeavours.

In a nut shell, based on the data and figures obtained during the semi-structured interviews, it is clear that patenting activities among Malaysian local breeders have started to gain pace and popularity and it is not surprising that they would become trends in the near future, in line with the view that strong patent protection would stimulate further innovation.

Issues and Problems in Patent Application:

As far as the legal framework is concerned, the Malaysian patent legislation consists of an interesting mix of provisions adopted from UK patent laws, with some uniquely national features. Hence, the RIs and agencies admitted that there are some common, typical problems inherent in the Malaysian patent law systems.

MARDI's officials were of the view that patent applications in Malaysia are quite costly. In this regard, MCB shared the same view with MARDI in highlighting the high cost for a patent application in Malaysia. This is aggravated by the difficulties in finding a qualified and skilful patent agent specialized in agricultural biotechnology. MPOB on the other hand highlighted other problems such as time-factor, as a patent application is time-consuming, right from the time it is filed until the final stage when the patent is granted. Another problem is lack of skills on the part of local patent agents in drafting patent application in the areas of biotechnological patent inventions. Interestingly, MOPB encountered no problem in applying for patents abroad, provided the patent application at the national phase is successful.

MRB and FRIM seem to share the same view with MPOB, stating that the time-frames are a challenge in patent applications. In the event that an application requires for further amendment, the whole process would be much longer in time and overall it is really time-consuming before a grant of a patent could take place.

It is important to note at this juncture that the problems of time-frame and 'time-consuming' in patent applications are in fact inherent and inevitable. In other words, delays in the patent granting process is a common problem faced by Malaysia. This is actually based on the patent legislation and system itself. In Malaysia, the average time to obtain a patent ranges from twelve to thirty months from PCT national phase entry, and from forty-two to sixty months from priority date for Paris Convention applications. After all, all Malaysian patent applications are subject to substantive examination, which is very time-consuming. The current examination system relies extensively on the results of search and examination of the same invention in certain recognized jurisdictions, which include patent offices of Australia, UK, Japan, Korea, the US and the EPO (IPO, 2009).

Patents in Agricultural Biotechnology:

As the pace of scientific discovery in agricultural biotechnology has accelerated over the past few decades, the use of patents and other IRRs to protect the inventions and techniques applicable to plant breeding and seed technology has increased tremendously, particularly in developed countries such as the US and European countries.

In this regard, RIs and agencies which are directly involved in the R&D of agricultural biotechnology play vital roles in realizing the country's aspiration and vision to become one of the global players in biotechnology. Therefore, Malaysia is committed to providing a strong IP protection regime under the Biotechnology Policy. As far as patent is concerned, MPOB is the leader in patenting its research outputs relating to agricultural biotechnology. MPOB has a total of 6 patents which directly relate to protect techniques applicable to plant breeding technology, namely palm oil. Interestingly, it has also applied for and been granted patents in countries such as Thailand, the US, Indonesia and the UK. MPOB plays a significant role in applying and promoting oil palm biotechnology. It has the whole complement of genes, promoters and transformation techniques for producing high oleic oil palm via genetic engineering. Research is on-going on oil palm specifically, and more patents are estimated to be filed as and when the research yields its desired objective.

Other RIs and agencies like MARDI, MRB, MCB and FRIM do not however own any patents on techniques in plant breeding technology, although they are also actively involved in research of agricultural biotechnology. MCB is thoroughly researching on transgenic cocoa plants and it expects to succeed in its research efforts some time in the near future (MCB, 2008). Some of the main area of research in cocoa biotechnology includes research in tissue culture and plant regeneration for the mass propagation of superior trees and as a platform for genetic engineering, pest resistant cocoa via in vitro technology and genetic transformation as well as research to produce high flavour Malaysian cocoa and specialty cocoa beans. The latest achievement by MCB is the success in creating partially transgenic cocoa somatic embryos, but transgenic plants have yet to be generated. MCB is anticipating another 10 years to create fully disease resistant cocoa trees before releasing them to farmers.

Plant Variety Protection: An Alternative:

The Protection of New Plant Varieties Regulations 2008 of Malaysia came into operation on October 20 2008, enabling Malaysia's Protection of New Plant Varieties Act 2004 to be implemented.

Since agriculture is one of the major sources of Malaysia's economy, there is a compelling need to protect the main crops such as palm oil trees, rubber trees and cocoa, not only in Malaysia, but also in other countries which are capable of growing such trees. The introduction of new varieties for these crops is an essential component to maintain and sustain good and high crop productivity and quality.

At this juncture, it is to be noted that since the filing of applications to register new plant varieties and grant of breeder's rights in Malaysia only began at the end of year 2008 and the interviews for the purpose of data collection were carried out some time from early towards the end of the year 2008, there was no specific questions on the implementation were asked to the RIs on plant variety protection. Nevertheless, some responses and views on plant variety rights system of protection were gathered and would be incorporated in this article. The statistics as provided by the Department of Agriculture (DOA) on their website regarding the current status and numbers of plant varieties application serve as major source on the figures and data relevant for this article. Currently, the cumulative number of applications received by the DOA is 70, and there has yet to be any grant of plant breeder's right, as all applications must undergo processes of examination as spelt out under the 2004 Act as well as the 2008 Regulation.

The following data is the summary of the applications with regard to MARDI, MPOB, MRB, MCB and FRIM.

Table 4: Number of plant varieties application by major RIs in Malaysia.

Research Institutes / Organization (RIs)	Total number of new varieties application submitted to DOA (as at August 2010)	Details of application (types of plant varieties)
MARDI	16	2 ornamentals 1 vegetable and 13 cereals (rice)
MPOB	0	-
MRB	0	-
MCB	4	Cocoa
FRIM	0	-

Source: Department of Agriculture (DOA's) website

It is not surprising to note that out of the total of 70 applications received by DOA, 14 applications come from MARDI, 4 applications from MCB, and there are no applications from MPOB, MRB and FRIM. This could be linked to the stand and views taken by MARDI and other remaining RIs on the effectiveness and necessity of the protection via plant breeder's rights. Their views are scrutinized in the following discussion.

Issues on Patenting of New Plant Variety:

The Malaysian Patents Act 1983 expressly states that plant varieties are not patentable. Hence, it seems that there was lack of formal protection for the new plant varieties in Malaysia prior to the implementation of the

2004 Act, despite the fact that the informal registration of new fruits varieties has been available for certification purposes since the early 1930's. MARDI which had been involved in research of all types of crops which include fruits and vegetables (except oil palm, rubber and cocoa) was looking forward to the implementation of the 2004 Act. Thus, it is not surprising that MARDI has started to submit its applications for plant breeder's rights after the Regulation 2008 came into force. In fact, MARDI has been in the forefront in terms of application for plant breeder's rights as compared to other research institutes like MPOB, MRB, MCB and FRIM.

MARDI takes a firm stand on the ban on patenting plant varieties, holding that the ban should be retained, and all the new plant varieties should be legally protected under the 2004 Act. MARDI is of the view that the 2004 Act provides an effective system of protection for the development of the breeding of the new varieties of plant. The scope of protection offered under the Protection of New Plant Varieties Act 2004 is comprehensive, extending to acts carried out on a commercial basis including producing or reproducing, conditioning for the purpose of propagation, offering for sale, marketing, exporting, importing and stocking the material for the earlier activities. Hence, unauthorized conduct of such acts will constitute an infringement under the 2004 Act.

In addition, MARDI is in full support of the 2004 Act as the limitation that serves as the exclusion to the infringing acts under the Act does facilitate the development of new plant varieties and related research. The 2004 Act specifically states that the rights do not extend to any act done privately on a non-commercial basis or for an experimental purpose or any act done for the purpose of breeding other plant varieties, propagation by small farmers using harvested material of the registered plant variety planted on their own holding, exchange of reasonable amount of propagating materials among small farmers and the sale of farm-saved seeds in situations where non-usage is beyond the control of the farmer. In this regard, MARDI comes under the exception of 'experimental purpose' hence its research activities should not be affected.

MARDI's view on retaining the ban on patenting of new plant varieties could be attributed to the fact that it was primarily established to conduct research to benefit the local farmers' community, by way of providing better variety of crops to upgrade farming activities and yield enhancements. In line with this objective, MARDI does not look at patents as the most suitable tool to help the local farming community in Malaysia, as patenting research output such as seeds would increase the price of a patented seed supply. Any increase in the price may not be in favour of the farmers' interest, and that would not help the local farmers, in particular subsistence and small-scale farmers, as the benefits of a patented seed supply could be insufficient to compensate for its higher price.

One practical example to show MARDI's practice and approach in managing its R&D output is the commercialization of a new variety of sweet potato named 'Vitato' in 1994 (MARDI, 20115).This new variety is more nutritious than other types of existing sweet potato variety because of its high B-carotene content as well as the ability to produce a much higher yield. Since the new PNPVP Act 2004 was not available when the variety was released for commercialization, obviously it was neither protected under PVP nor under the Patents Act 1983 which expressly exclude plant varieties from patentability. The interesting part of this invention by MARDI was that it was publicly available for local farmers for growing purposes via arrangement with MARDI. At this juncture, it is crystal clear that MARDI Agricultural Technology research team is giving priority to improve the living of local farming community via free access to the new variety rather than going into protecting its invention by way of patents or any other means available. The same approach is taken by MARDI in managing and distributing its new rice varietyto local farmers throughout the country without any licensing fees whatsoever, with the primary objective of improving the paddy/rice breeding and increasing the productivity level of local rice.

MPOB and MRB on the other hand hold an opposite view of MARDI. Both of these research institutes are proponents of patent protection for their research invention. MPOB and MRB are of the view that the ban on patenting of new plant variety should be lifted in order to give new varieties of plant a strong IP protection via patent system. In addition, they argue that protection via patent regime would generate more income and profit to the country and better economic gain as a whole. Their stand is parallel with the fact that as compared to MARDI which aims to serve and protect the interests of the farmers' community, MPOB and MRB work directly with and for the industry players in their specialized agricultural sector, hence there is a pressing, real need for both of the institutions to secure the strongest protection available for their research efforts and outcome. Having said that, patent protection is perceived as generally providing stronger and better protection compared to plant breeder's rights, though this perception continues to be a contentious issue worldwide.

MCB shares the same view with MPOB and MRB, holding that the ban on patenting of new plant varieties should not be retained, for the reason that their forth-coming new high value cocoa varieties deserve strong protection through the patent right for the country's benefit in the long run. This is because as far as commercialization of research and development of any invention is concerned, patents could be used to recoup the investment as well as generating income via licensing. FRIM on the other hand holds opposite view, stating that the ban on patenting should remain on ethical reasons, *inter alia*, patent should never be allowed on life forms which include plant varieties.

To sum up, there are basically two opposite views on the ban on patenting of plant varieties, some of the research institutes are in favour of lifting the ban, while some are of the view that the ban should be retained. As far as the Malaysian Patents Act 1983 is concerned, the issue and discussion remains hypothetical at this moment of time, as the existing law states firmly that plant and animal varieties are non-patentable inventions. In this regard, it is worth noting that neither the Patents Act 1983 nor the Protection of New Plant Varieties Act 2004 makes it clear whether an invention in the form of a genetically modified plant that has, for example, increased resistance to certain types of pests, is patentable if the genetic modification (involving significant human intervention) used to achieve the result can be applied to plants in general and is not confined to any particular variety. It would seem that such inventions may be patentable, provided they fulfill other requirements of the Patents Act 1983, such as novelty, inventiveness, industrial applicability and requirements relating to non-contravention of public order and morality.

As far as the Protection of New Plant Varieties Act 2004 is concerned, although the filing of applications to register new plant varieties and grant of breeder's rights in Malaysia have begun since the Regulation came into operation in 2008, it is too early at this stage to ascertain the problems, if any, that may arise in the implementation of the Act. Undoubtedly, the implementation of the Act could be seen as another milestone for Malaysia's agricultural sector and the country's National Biotechnology Policy as well as its IP protection system as a whole.

Patent Law versus Plant Breeder's Rights:

The relationship and interface between patent law and plant breeders' rights is essentially inevitable in light of modern developments in biotechnology. From the responses that have been gathered during the interviews, some of the RIs and agencies are apprehensive about patenting varieties of plants though they acknowledge that genes and gene transfer technology at a biotechnological level should be covered by a patent system. In general, plant varieties have hitherto been excluded from the grant of a patent by most patent systems, which include Malaysia, for reasons that seem to be unclear. Given a choice between the two types protection for their agricultural biotechnological inventions, MARDI, being the proponent of plant breeders right, would obviously opt for the plant variety right system of protection on the reason that such a system is seen to offer the most suitable type of protection for all new plant varieties researched and developed by MARDI. Besides, it is not thought to be in the public interest at large and Malaysian farmer's community in particular to permit such an extensive monopoly over plant varieties, given their communal importance. This view is also adopted by FRIM, taking into consideration the scope of protection covered under the Protection of New Plant Varieties Act 2004.

Surprisingly, MRB shares the same view with MARDI, holding that plant breeder's right would be preferable on the basis of simpler procedure and lower fees, as compared to higher cost incurred in a patent application. MPOB being the proponent of patent protection maintains that patent is still preferable even if the plant invention is equally qualified to be protected under the plant breeder's right system of protection. MCB concurs with this view, justifying its stand on the enormous amount of time and money spent into researching and developing its new high value cocoa varieties. Having invested a considerable amount of money and time in developing innovative products, a patent on the research output would enable commercialization of the invention to obtain returns on investments as well as to generate profits.

Interestingly, despite the mixed reaction towards the patent system and plant breeder's right, there is a unanimous recognition from all the research institutions and agencies that patents provide much stronger protection than plant breeder's right for the products of biotechnological research.

The gathered responses from the RIs on their preferred system of protection for their invention are to some extent translated in the current number of application of new plant varieties as received by the Department of Agriculture (Refer Table 4) above).

To recap, the exclusion from patentability under Malaysian Patents Act 1983 is sufficiently clear to cover plant varieties, yet an invention involving plants seem to be patentable. What remains unclear is whether genetically modified plants can be both patentable as well as registrable under the Protection of New Plant Varieties Act 2004 (AZMI, Ida Madieha Abdul Ghani, 2004). In this regard, it would appear that Malaysia's position would be consistent to that of international practice. A genetically modified variety would not be patentable but a plant invention that consists of genetically modified cell-lines would be. A clear legal position on this area is vital for plant breeders in Malaysia, to assist them in selecting the best and most suitable IPR in protecting their agricultural biotechnological inventions.

Commercialization Of Agricultural Biotechnological Inventions In Malaysia: Issues And Challenges:

Despite having a vibrant research community, Malaysia has lagged behind the international community in terms of translating research into new patents and companies. Among the factors contributing to the poor commercialization rate was the lack of co-located inventors and effective entrepreneurial strategies. This could

be attributed to the fact that traditionally commercialization was not the main focus or high priority of these government-funded institutions. In fact, there was to some extent a communication gap between scientists, researchers and academicians on one hand and the commercial sector involving entrepreneurs and business people from the relevant industry on the other.

Realizing the issues and challenges in commercialization of biotechnological products, the Government has taken some pro-active strategies, inter alia, the establishment of the National Biotechnology Directorate (NBD) in 1995 under the Ministry of Science, Technology and the Environment. One of the NBD's goals is on commercializing government-funded biotech research, other than strengthening research capability and capacity in biotechnology, as well as facilitating the development of biotechnology-based industry.

Other strategies which have been implemented by the Malaysian government are by ways of grants aimed at translating research to commercialization. The Intensification of Research in Priority Areas (IRPA) is one of the biggest research funds, and the NBD also manages a research fund dedicated to biotechnology. For example, under the Eighth Malaysia Plan, IRPA has an allocation of RM1 billion, RM310 million of which is earmarked for the commercialization of biotech and other projects through the Industrial Grant Scheme (IGS) and Commercialization of Research and Development Fund (CRDF) (Tang, C.M., 2003).

Coming back to the RIs, based on the information obtained during the interview, all the five RIs and agencies have been commercializing their research products via licensing. Therefore, licensing of patent rights is the most popular and common commercialization pathway among the main research institutions in Malaysia. After all, patent licensing is the most prudent method of generating income from an invention that is via royalties. MPOB and MCB are in the forefront in terms of patent licensing, as they even license their patents abroad. MARDI, MRB and FRIM have yet to license their patent rights abroad.

Another method of commercialization of MARDI research product is via assignment, which is by way of sale and transfer of ownership of the patent by the assignor to the assignee. In fact, assignment is sometimes preferable by MARDI researchers in commercializing their research products for the reason that such a permanent transfer of their patents to the assignee would release them from the responsibility of monitoring the patented inventions in the event there is any patent infringement.

As for MPOB, other than patent licensing, it also generates income from their research inventions via lump sum sale payment or direct sale. The reason is to avoid the risk of uncertain royalties with a licence; hence MPOB in certain research inventions prefers to receive a once only lump sum payment, at the outset, receiving all the value of the patent on one single occasion only. MCB is taking the same approach with MPOB in generating income from their patented inventions. With regard to MRB, in order to boost commercialization for its R&D products, MRB has gone to the extent of setting up certain sub-companies to handle marketing strategies and matters related to commercialization of its inventions. This is for the reason that its researchers are lacking in marketing skills and strategies, hence experts in those areas would do a better job in promoting and commercializing MRB’s inventions.

It is interesting to note that all the five RIs and bodies are unanimous in viewing that the patent regime is the best method and most effective protection for their agricultural biotechnological inventions, as compared to other alternative methods like trade secret or contractual agreements. MPOB being the proponent of patent holds that patent is always given priority to protect their R&D products. MRB and MCB concur on this view, with some other additional reasoning, such as patent would enable the investors to recoup their investment and make profits. Ultimately, patent would benefit the country to generate more income in the long run. On the other hand, most of the research institutions and agencies are of the view that trade secret protection is too complicated, risky and unreliable to protect their research products, whereas contractual agreements are not favourable for the reason that such agreements are limited and only enforceable between the contracting parties.

It was also revealed that, as far as MARDI is concerned, the move to commercialization has not resulted in any significant licensing revenue for MARDI, although it has licensed certain patents to some local companies. One reason cited is that the products which are produced by local companies under MARDI patent licensing are having a difficult time to penetrate the market and to compete with existing products. The problem could be attributed to the fact that local companies generally lack capabilities and competitiveness in marketing due to limited funds to be allocated for aggressive marketing strategies.

Essentially, public sector research and development activities have contributed to technical improvements. Nevertheless, progress on the commercialization of such output was limited. This was largely due to problems related to the lack of industry-relevant research and development projects and finance to fund the various stages of commercialization from the laboratory to the market place. A survey of 5,232 projects implemented by the public research institutions and universities during the Sixth and Seventh Malaysian Plans (year 1990-2000) revealed that 14.1 per cent of these projects were identified as potential candidates for commercialization while only 5.1 per cent were commercialized. However, an assessment of research and development undertaken in the primary commodity sub-sector indicated that the percentage of commercialization of research and development in industrial agricultural commodities was 8.9 per cent. In this regard, the palm oil sector contributed the highest commercialization rate of 12.1 per cent.

In a nut shell, one of the major causes underlying this unfortunate state of affairs is the lack of a strong entrepreneurial environment and mechanisms for commercialization. In this regard, the Government's continuous support and commitment for strong R&D programs at various RIs and universities in agricultural biotechnology should exploit the potential from biotechnology towards accelerating the development of agricultural biotechnology industry in Malaysia. In addition, RIs are obliged to place more emphasis on research related to product and process development for industry in order to generate more research and development projects that can be commercialized.

Conclusion: The Way Forward:

The future looks promising for agricultural biotechnology in Malaysia, especially with strong endorsement by the Government. The Malaysian Government recognizes biotechnology as a high-end technology to be fully exploited in the twenty-first century, supported with full commitment from various RIs, public universities as well as a number of private companies. Being a country with strong agrarian roots and with the push into agricultural biotech, it is natural for Malaysia to leverage its traditional strengths in the agricultural sector. This article has analyzed the viewpoint of plant breeders in Malaysia on patent protection for agricultural biotechnology R&D outputs as well as their views on plant breeders' right system which has just been implemented.

It is found that patenting activities of R&D inventions in the major RIs and agencies have already taken place for quite some time, but they started to gain popularity and become a trend from the year 2000s onwards. The findings could be seen as positive indicator of the awareness on the importance of protecting their inventions via IPRs notably patents. Besides, patents are viewed as one of useful indicators for identifying the fields where technological advances are being made, and this includes agricultural biotechnology.

The patent regime seems to be preferred by the majority of the RIs for the reason that it offers strong and reliable protection over inventions, as well as the opportunity to recoup the investment and make profits. Nevertheless, as far as the legal framework is concerned, there is a need to further clarify the scope of patentable and non-patentable inventions under Patents Act 1983, to the effect that an invention in the form of a genetically modified plant would be patentable provided the invention is not confined to any particular variety.

The effectiveness of protection offered under the Protection of New Plant Varieties Act 2004 is yet to be seen, but this pan-Malaysian, *sui generis* form of protection is specifically tailored for breeders of new plant varieties in Malaysia. The protection offered under the 2004 Act, compared to the patent system, may be preferable among plant breeders for some reasons, *inter alia*, the lesser cost incurred in registering for a plant variety right. Nevertheless, the time factor to fulfill the requirements of uniformity and stability of a plant variety is a concern which is relevant to be taken into account in ascertaining the best method of protection for such a variety or transgenic plant.

With regard to commercialization of R&D inventions, public sector RIs has produced significant amounts of research on resource-based industries. However, the initiative to commercialize such findings remains limited due to the high costs and risks involved. The Government's role and initiatives are inevitable to provide assistance and support to Malaysian-owned companies to enable them to step forward to spearhead and stimulate the commercialization of findings of local R&D.

In all, the Malaysian biotechnology industry is on track to accelerate commercialization in biotechnology with the full support of the National Biotechnology Policy and BiotechCorp.

References

A cess at the rate of 3.85 cents shall be imposed on every kilogramme of natural rubber exported from Peninsular Malaysia. (Order 2(1) of Malaysian Rubber Board (Cess) Order 2000 under Malaysian Rubber Board (Incorporation) Act 1996).

All RIs have their own website, detailing their research focus and R&D activities. MARDI : <http://www.mardi.my>; MPOB: <http://www.mpob.gov.my>; MRB: <http://www.lgm.gov.my>; FRIM: <http://www.frim.gov.my>; MCB: <http://www.koko.gov.my>.

As at 15th August 2011, refer : <http://pvpbkkt.doa.gov.my/>

As at 15th August, 2011.

As confirmed by the MCB during the interview via email in August 2008.

At the time of the interview (June 2008), the Act was yet to be implemented as the 2008 Regulation was only released in October 2008. Hence the view is to some extent based on estimation and expectation.

AZMI, Ida Madieha Abdul Ghani, 2004. The Protection of Plant Varieties in Malaysia, The Journal of World Intellectual Property, 7, pp. 877-890, at p. 882.

INNES, N.L., Plant Breeding and Intellectual Property Rights. Available at: < http://www.agric-econ.uni-kiel.de/Abteilungen/II/forschung/file5.pdf> [Accessed 15 August 2011]

Ironically, scientists from India, China and the United States have discovered that Bt crops ie genetically engineered with *Bt* toxin proteins from the soil bacterium *Bacillus thuringiensis* targeted at insect pests, often failed to protect against pest attacks, and have other problems as well. Refer :< http://www.i-sis.org.uk/SCFOBTC.php> [Accessed 15 August 2011].

It is to be noted that MPOB's legal advisor (with whom the interview was made) admitted her lack of knowledge on the plant breeder's right system and its scope of protection, on the reason that it was yet to be implemented in Malaysia. This is to some extent justifiable, as at the time of the interview (June 2008), the Act was yet to be implemented, because the 2008 Regulation was only released in October 2008.

On average, a lawyer's fee for drafting a patent description would be between RM5000 and RM10, 000. To get an invention patented, a rough estimate of the cost is between RM8, 000 to RM9, 000. This is however excluding professional translation fees. The total cost however may go up to RM 40, 000 depending the various types of patents. Source : Shearn Delamore & Co, as reported in the newspaper, available at : http://www.bic.org.my/BICalert/0107/080107NST-0.pdf [Accessed 15 August 2011]

Other Malaysian applicants include Sabah Forestry Development Authority, Felda Agricultural Sdn Bhd, Universiti Kebangsaan Malaysia, private companies (Malaysian Agrifood Corporation Berhad, Ligno Biotech Sdn Bhd) and foreign applicants from the US and Netherlands. Source : DOA at <http://pvpbkkt.doa.gov.my/> [Accessed 15 August 2010]

Privately-owned Corporation which is also focusing on oil palm research in Malaysia is Sime Darby. It has recently reported its success on oil palm genome research which is instrumental to boost palm oil yields, better planting materials and generation of new variety of crops. Refer : <http://biz.thestar.com.my/news/story.asp?file=/2009/5/14/business/3896765&sec=business> [Accessed 15 August 2011]

Refer : <http://palmnews.mpob.gov.my/palmnewsdetails/print.php?idnews=3072> [Accessed 15 August 2011]

Refer : <http://pvpbkkt.doa.gov.my/>

Refer : <http://www.koko.gov.my/CocoaBiotech/AcDOCTRTPB.html> [Accessed 15 August 2011]

Refer : <http://www.koko.gov.my/CocoaBioTech/Program.html>[Accessed 15 August 2011]

Refer MARDI Agricultural Technology Website (MAGRITECH) : <http://agromedia.mardi.gov.my/magritech/tech_detail_fdcrop.php?id=328> [Accessed 15 August 2011]

Section 11 and Section 31 Patents Act 1983.

Section 13(1)(b) Patents Act 1983.

Section 13(2)(b) of Patents Act 1983.

Section 31(1) Protection of New Plant Varieties Act 2004.

Since its establishment in 1970s, MARDI has released more than 30 high-yielding rice varieties. Refer : http://agromedia.mardi.gov.my/magritech/fdcrop.php [Accessed 15 August 2011]

Source : 9th Malaysia Plan, Economic Planning Unit. Refer http://www.bnm.gov.my/files/publication/sme/en/2005/chap_8.pdf [Accessed 15 August 2011]

Tang, C.M., *et al.* 2003. Realizing potential: the state of Asian bioentrepreneurship. [Online], Available at: <http://www.nature.com/bioent/2003/030401/full/bioent731.html> [Accessed 15 August 2011].

Tax imposed on palm oil producer, for example, in 2009, at the rate of RM15 per tonne of palm oil and palm kernel oil produced at the mills and crushers. Refer : <http: //www.neac.gov.my/files/Palm_Oil_Industry.pdf> [Accessed 15 August 2011]

The fact is confirmed by the RIs during the semi-structured interviews as carried out in 2008.

The figure is based on a report in a newspaper, which is available at : <http:// www.bic.org.my/BICalert/0107/080107NST-0.pdf>[Accessed 15 August 2011]

The figure is correct as at Jun 2008, obtained during the semi-structured interview sessions with MPOB official.

The Government, via MyIPO, has set up a special committee for the purpose of reviewing and proposing any amendment to the current IPR statutes namely Patents Act 1983, Trade Marks Act 1976, Copyright Act 1987, Industrial Designs Act 1996. The Patents Act 1983 will be undergoing some amendment, as confirmed by MyIPO via email communication on 6th September 2010.

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The information is based on the data collected from the semi-structured interview sessions and respective RI's websites.

The patent was concerning the improvements relating to the treatment of rubber latex. Source : <http://www.lgm.gov.my/general/NRHistory.aspx> [Accessed 15 August 2011]

[1]The relevant report is available at : < http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/country%20report%20double.pdf> [Accessed 15 August 2011]

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The same approach was taken by MARDI when another new variety of sweet potato which is virus-free was released in 2005, as the 2004 Act was yet to be implemented at that time.

The survey is based on an online article by Aziz, Dato'Mohd Rosli Abdul. Funds for Agro Bio Industry. Available at: <http://banktani.tripod.com/bio.htm> [Accessed 15 August 2011]

This was confirmed by Patent Division, MyIPO during the interview session carried out in July 2009.